

AMENDMENT UNDER 37 C.F.R. § 1.116  
U.S. APPLN. NO. 09/816,655

REMARKS

Reconsideration is respectfully requested.

Initially, Applicants remind the Examiner that on December 13, 2002, Applicants filed a Request for Withdrawal of Finality of the Office Action of November 5, 2002. For the convenience of the Examiner, a copy of that request including the filing receipt therefor, is attached hereto. It is believed that upon careful review, the Examiner will agree that the finality should be withdrawn of the Office Action of November 5, 2002.

With respect to the amendments of the claims, the Examiner is first of all requested to note that generic claim 1 now in the application has been amended to recite that the claimed method thereof is directed for treatment of a subject having an eye disorder associated with apoptosis. This necessitated minor amendment in claim 16. In addition, claim 19 dependent on claim 16 has been added specifying the eye disorder caused by light is photoretinitis. The amendment to claim 1 is supported by, *inter alia*, page 20, lines 14-18 and page 21, lines 6-13. New claim 19 is supported by page 24, line 17.

In the Office Action of November 5, 2002, claims 1-18 stood rejected under the first paragraph of 35 U.S.C. § 112 for the reasons set forth on page 2 of the Office Action of February 27, 2002. At that portion of the February 27, 2002 Office Action, the claims were rejected because in the Examiner's view point the specification was not enabling for the phrase "a disease or condition associated with apoptosis". The Examiner submitted an undue experimentation would be required to practice the scope of the invention commensurate with that language. The remaining rejected claims are directly or indirectly dependent upon claim 1. Applicants submit that the 35 U.S.C. § 112, first paragraph, rejection is rendered moot by the narrowing amendment

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to claim 1. The Examiner is also referenced to the portions of the specification noted above with respect to support for the amendment to claim 1, plus the working example in the application which is directed to an ophthalmic condition.

Reconsideration and withdrawal of the 35 U.S.C. § 112, first paragraph, rejection is respectfully requested.

At page 2 of the Office Action, claims 1-15, 17 and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by European Patent Application 0435443. The Examiner submits that the European Application teaches the use of claimed prostaglandins for the treatment of conditions associated with apoptosis. In addition, the Examiner submits that ophthalmic use is also taught by the reference.

First of all, Applicants note that claim 16 was not rejected over the prior art. It is believed that claim 16 is not rejected over the prior art because of the subject matter thereof being concerned with apoptosis related to an eye disorder. A concept of an eye disorder being the disease or condition has been inserted in to claim 1, and on that basis Applicants submit that new claim 1 is novel over EP '443.

Furthermore, Applicants must also respectfully submit that EP '443 does not disclose or suggest ophthalmic use of a prostaglandin compound. Accordingly, all claims are novel over the cited EPA reference. Furthermore, in the event the Examiner should consider a 35 U.S.C. § 103 rejection based on EPA '443, Applicants submit that such a rejection would also be untenable since there is no teaching or suggestion in EPA '443 to utilize prostaglandins of any type for treatment of an eye disorder associated with apoptosis. With respect to the Examiner's

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comments at the middle of page 2 of the Office Action, regarding ophthalmic use of prostaglandins, Applicants believe the Examiner may have intended to refer to EPA 0308135, also submitted with an Information Disclosure Statement of April 24, 2002. In this regard, Applicants note that EPA 0308135 merely discloses the use of the compounds set forth therein for reduction of intraocular pressure or for treatment of glaucoma, but does not disclose or suggest use for apoptosis related conditions.

From the above, Applicants submit that they have overcome the rejections of the Office Action of November 5, 2002.

Next, Applicants add at this time claims 20-39 directed to a method for inhibiting apoptosis in a subject having a disease or condition associated with apoptosis by administration of an effective amount of a 15-keto-prostaglandin compound of formula (I).

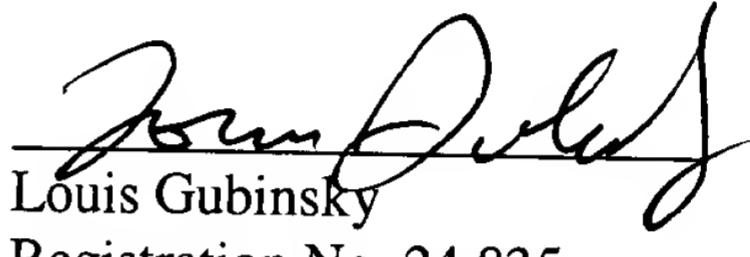
Applicants respectfully submit that such claims should be considered at this time because the finality of the Office Action under consideration should be withdrawn. These claims are supported, for example, by page 24, lines 5-17, the working example and page 26, lines 12-14. Entry and allowance of claims 20-39 are respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

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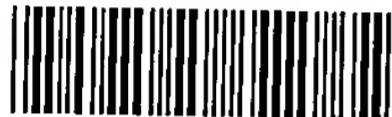
The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

  
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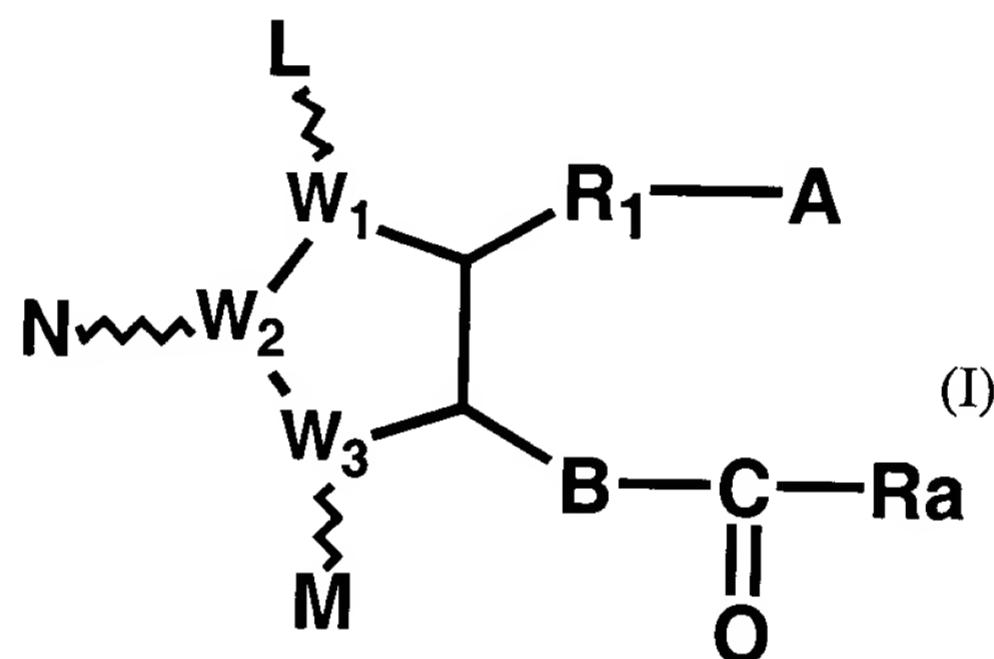
Date: March 5, 2003

**APPENDIX**  
**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

**The claims are amended as follows:**

1. A method for treatment of a subject having ~~a disease or condition~~ an eye disorder associated with apoptosis, which comprises administering an effective amount of a 15-keto-prostaglandin compound represented by the following formula (I):



wherein  $W_1$ ,  $W_2$  and  $W_3$  are carbon or oxygen atoms;

$L$ ,  $M$  and  $N$  are hydrogen, hydroxy, halogen, lower alkyl, lower alkoxy, hydroxy(lower)alkyl or oxo, wherein at least one of  $L$  and  $M$  is a group other than hydrogen, and the five-membered ring may have one or more double bond(s);

$A$  is  $-CH_2OH$ ,  $-COCH_2OH$ ,  $-COOH$  or its functional derivative;

$B$  is  $-CH_2-CH_2-$ ,  $-CH=CH-$  or  $-C\equiv C-$ ;

$R_1$  is a divalent saturated or unsaturated lower-medium aliphatic hydrocarbon residue, which is unsubstituted or substituted by halogen, alkyl, hydroxy, oxo, aryl or heterocyclic group; and

$R_a$  is a saturated or unsaturated lower-medium aliphatic hydrocarbon residue, which is unsubstituted or substituted by halogen, oxo, hydroxy, lower alkyl, lower alkoxy, lower

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alkanoyloxy, cyclo(lower)alkyl, cyclo(lower)alkyloxy, aryl, aryloxy, heterocyclic group or heterocyclic-oxy group; cyclo(lower)alkyl; cyclo(lower)alkyloxy; aryl; aryloxy; heterocyclic group; or heterocyclic-oxy group to the subject.

16. The method of claim 1, wherein the ~~disease or condition~~ eye disorder associated with apoptosis is an eye disorder caused by light.

**Claims 19-39 are added as new claims.**